UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,166	09/19/2003	Andrew H. Segal	11111/2003I	8303

29933 7590 03/21/2007

PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,166	SEGAL ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *42-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 73-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The response filed on 12/21/06 to the restriction requirement of 6/15/06 has been received. With traverse Applicant has elected the following species: (1) Melanoma, (2) amino acid sequence which can bind to a sialic acid, and (3) ligand for GM-CSF receptor. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the restriction is maintained (MPEP 818.03(a).

Due to an overlapping search, the species "the ligand for a cell surface polypeptide IL-2" has been rejoined.

Claims 1-77 are pending.

Claims 42-72 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention. It is noted that claims 34-72 provide limitations to unelected species.

Claims 1-41 and 73-77 are currently under consideration.

Specification

The specification is objected to on pages 167-170, 178-180, 182, 185-187, 192, and 193 for improper disclosure of polynucleotide sequences, as it fails to comply with the requirements of 37 CFR 1.821 through 1.825. This definition sets forth limits, in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an

unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. (see MPEP 2422). Proper correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 12-20, 32, 38, 39, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected for reciting: "wherein said tumor is derived". There is insufficient antecedent basis for this limitation in the claim. Although the claim upon which claim 5 depends recites "a tumor cell" and "a cell", it is not clear what is meant by "said tumor".

Claim 7 is objected to for reciting: "...wherein said fusion polypeptide is endogenous to said cell". The specification discloses, and one of skill in the art would recognize, that "endogenous" refers to something which is expressed or present naturally in a cell (page 6, in particular). However, one of skill in the art would recognize that "fusion polypeptides" are genetically engineered and not "expressed or present naturally in a cell". Therefore, it is unclear what is meant by an "endogenous" fusion polypeptide. This renders the claim indefinite and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

Claim 12 and dependent claims 13-20 are rejected because claim 12 recites the term "at least about 10...". It is not clear from the claims or the specification what "at least about 10" means since 9 would be "about 10", but would not be "at least" 10. This renders the claim indefinite because the term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

Claim 19 is rejected for reciting: "The composition of claim 18, wherein said influenza virus is of an H2 or H3 subtype". Since the influenza virus of claim 18 is of an H1 subtype, it is unclear how it can also be of an H2 or H3 subtype. Given the above reasons, the metes and bounds of the claims cannot be determined.

Claims 32, 38, and dependent claim 39 are rejected because claims 32 and 38 recite the term "at least about five...". It is not clear from the claims or the specification what "at least about five" means since 4 would be "about five", but would not be "at least" five. This renders the claim indefinite because the term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the

requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

Claim 76 is rejected for reciting: "The composition of claim 1, in which at least some of said fusion polypeptide is not bound to said antigen bearing target". Since claim 1 recites a composition comprising an antigen bearing target and "a" fusion polypeptide, it is unclear how "some" of said polypeptide is not bound to said antigen-bearing target. It is unclear whether claim 76 is drawn to a composition comprising a fusion polypeptide that comprises more than a binding region for an antigen-bearing target, wherein a non-binding region of the polypeptide is "some" of said polypeptide that is not bound to said antigen-bearing target. Alternatively, it is unclear whether claim 76 is intended to be drawn to a composition comprising an antigen-bearing target and more than one fusion polypeptide, some of which are not bound to said target. This renders the claim indefinite and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-41 and 73-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of compositions comprising an antigen bearing target and further comprising a fusion polypeptide comprising a first amino acid sequence which is selected from: a carbohydrate binding domain of a collectin; a carbohydrate binding domain of a galectin; a carbohydrate binding domain of a C-type lectin; or an amino acid sequence which can bind to a carbohydrate on a glycoprotein, said carbohydrate being chosen from the group: D-mannose, D-glucose, D-fucose, L-fucose, N-acetyl-beta-D-glucosamine, N-acetyl-beta-D-glucosamine, a sialic acid; and a second amino acid sequence comprising a ligand for a cell surface polypeptide, said ligand being chosen from the group: a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for a heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule.

The written description reasonably conveys the following species of the claimed genus: (1) a composition comprising murine GM-CSF fused to the Gas1 GPI modification signal and CMS-5 murine fibrosarcoma cells (Example 3), (2) a composition comprising GM-K-HA and CMS-5 murine fibrosarcoma cells (Example 14);

and (3) a composition comprising GM-CSF-K-Ha and CMS5 cells (Example 15, in particular).

The state of the prior art is such that one of skill in the art would not know from the recitation of the claims, in view of the specification, what would encompass the claimed genus, which comprises three broad components: (1) an antigen bearing target, (2) a first amino acid sequence which is selected from: a carbohydrate binding domain of a collectin; a carbohydrate binding domain of a galectin; a carbohydrate binding domain of a C-type lectin; or an amino acid sequence which can bind to a carbohydrate on a glycoprotein, said carbohydrate being chosen from the group: D-mannose, D-glucose, D-fucose, L-fucose, N-acetyl-beta-D-glucosamine, N-acetyl-beta-D-glucosamine, a sialic acid, and (3) a second amino acid sequence comprising a ligand for a cell surface polypeptide, said ligand being chosen from the group: a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for a heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule. An antigen bearing target is broadly drawn to anything that would be antigenic to an identified subject. Further, it is noted that recitation that an amino acid sequence "can" do something (for example, bind to a certain moiety) is not a limitation to said amino acid sequence. Therefore, an amino acid sequence which "can bind to a carbohydrate on a glycoprotein, said carbohydrate being chosen from the group: D-mannose, D-glucose, D-fucose, L-fucose, N-acetyl-beta-D-glucosamine, N-acetyl-beta-D-glucosamine, a sialic acid" broadly reads on any amino acid imaginable. Further, one

of skill in the art would recognize that "ligands" for particular molecules or receptors broadly reads on anything that would bind said molecules or receptors. Therefore, "a ligand for a cell surface polypeptide, said ligand being chosen from the group: a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for a heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule" broadly reads on undisclosed antibodies and antibodies not known in the art, undisclosed small molecules and small molecules not known in the art, undisclosed growth factors and growth factors not known in the art, undisclosed cytokines and cytokines not known in the art, and undisclosed chemokines and chemokines not known in the art. However, although not representative of the broadly claimed genus, the state of the art teaches a few compositions encompassed by the claimed genus (see the anticipation rejections below).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of compositions that encompass the genus nor does it provide a description of structural features that are common to said genus. Further, it is noted that recitation of an amino acid sequence "which can ...(bind, for instance)" does not provide any type of limitation to said amino acid sequence. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of (1) a composition comprising murine GM-CSF fused to the Gas1 GPI modification signal and CMS-5 murine fibrosarcoma cells (Example 3), (2) a composition comprising GM-K-HA and CMS-5 murine fibrosarcoma cells (Example 14); and (3) a composition comprising GM-CSF-K-Ha and CMS5 cells (Example 15, in particular) is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that

[he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 22, 24-30, 32, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Ali et al (Cancer Research, 3/15/00, 60:1663-1670), as evidenced by Cantrell et al (PNAS, 9/85, 82:6250-6254).

Ali et al teaches a composition comprising an M3 malignant melanoma cell (an antigen bearing target) and further comprising a fusion polypeptide comprising a first N-terminal amino acid sequence comprising genetically inactivated HSV-2 (an amino acid sequence which "can" bind to any sialic acid) and a second amino C-terminal acid sequence comprising mouse GM-CSF (a ligand for a the mouse GM-CSF cytokine receptor) (right column of page 1667, in particular). One of skill in the art would describe said fusion polypeptide as "exogenous" to M3 malignant melanoma cells since the construct was recombinantly introduced to said cells (right column of page 1667, in particular). Further, since said fusion polypeptide is expressed by a polynucleotide construct within said M3 melanoma cell, one of skill in the art would describe said fusion polypeptides as "endogenous" to said M3 malignant melanoma cell and that it is encoded by a nucleic acid sequence comprised by the cell. Further, said second sequence comprising mouse GM-CSF would bind mouse GM-CSF receptor polypeptides found on any cell type. Further, as evidenced by Cantrell et al, mouse GM-CSF comprises at least about five contiguous amino acids of a human GM-CSF (see Figure 2 of Cantrell et al). Further, since said fusion polypeptide comprises two distinct polypeptide sequences which do not overlap, one of skill in the art would refer to the region between said sequences as "a linker". Further, one of skill in the art would

recognize that at least some of the fusion polypeptide is found within said cells, where it is translated, before it is bound to antigen bearing targets on said cells.

Claim Rejections - 35 USC § 102

Claims 1, 2, 6-8, 10-18, 20-22, 24-27, 34, 35, 37-41, and 75-77 rejected under 35 U.S.C. 102(b) as being anticipated by Faulkner et al (International Immunology, 6/01, 13(6):713-721), as evidenced by the specification and Raymond et al (Nucleic Acid Research, 10/83, 11(20):7191-7203).

Faulkner et al teaches compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising a ligand for a cytokine receptor (pages 713-714, in particular). Faulkner et al teaches said second polypeptide sequence can be mouse interleukin-2 (IL-2) or GM-CSF (page 714, in particular). One of skill in the art would describe said fusion polypeptide as "exogenous" to the composition comprising E coli cells since the construct was recombinantly introduced to said cell and encoded by a nucleotide sequence comprised by said cell (right column of page 714, in particular). Further, one of skill in the art would describe said fusion polypeptide as "exogenous" to the composition comprising the immature murine dendritic cells since the fusion polypeptide was produced in another cell (right column of page 714 and page 716, in particular). Faulkner et al further teaches the first amino

acid sequence N-terminal to the second amino acid sequence (right column of page 714, in particular). Further, said first amino acid sequence "can" bind any sialic acid. Further, as evidenced by the specification at pages 7-9 and page 7194 of Raymond et al, said first amino acid sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 comprises a carbohydrate-binding domain of a naturally occurring lectin. As evidenced by Raymond et al, said A/PR/8/34 infects humans (page 7191,in particular). Further, it is noted that Faulkner et al teaches methods wherein said A/PR/8/34 virus does not infect humans. Further, said second amino C-terminal acid sequence comprising mouse IL-2 or GM-CSF would bind mouse IL-2 receptors or compatible GM-CSF receptors found on any cell type. Faulkner et al further teaches construction of said fusion polypeptide (right column of page 714, in particular). Further, one of skill in the art would recognize that said fusion polypeptide would not be bound to said E coli cells while it is inside said E coli cells. Further, Faulkner et al teaches a population of said fusion polypeptide not bound to E coli or immature murine dendritic cells (right column of page 714, in particular). Although Faulkner et al not specifically teach that the first polypeptide of the fusion protein is bound to said immature murine dendritic cells via a carbohydrate on said immature murine dendritic cells, the claimed product appears to be the same as the prior art, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material and structural characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicant

to prove that the claimed product is different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989). Faulkner et al further teaches said compositions are to be optimized to produce vaccines with protective immune responses (left column of page 714, in particular).

Claim Rejections - 35 USC § 102

Claims 1, 2, 6, 7, 9, 10, 21, 23-27, 34, 36, 37, 38-41, and 76 are rejected under 35 U.S.C. 102(a) as being anticipated by Hayashi et al (Protein Eng, 5/02, 15(5):429-436).

Hayashi et al teaches a composition comprising Sf9 insect cells (an antigen bearing target) and further comprising a fusion polypeptide comprising a first amino acid sequence comprising the N-terminus of human type III collagen (a first amino acid sequence which "can" bind to a sialic acid) and a second amino acid sequence comprising human IL-2 (a ligand for a cytokine receptor) (see page 429, in particular). One of skill in the art would describe said fusion polypeptide as "exogenous" to the Sf9 cells since the construct was recombinantly introduced to said cells (page 430, in particular). Further, since said fusion polypeptide is expressed by a polynucleotide construct within said Sf9 cells, one of skill in the art would describe said fusion polypeptide as "endogenous" to said Sf9 cells and that it is encoded by a nucleic acid sequence comprised by the cells. Further, Hayashi et al teaches that IL-2 is C-terminal to the N-terminus of human type III collagen in said fusion protein (page 430, in

particular). Further, said first amino acid sequence "can" bind any sialic acid. Further, said second N-terminal sequence comprising human IL-2 would bind human IL-2 receptors found on any cell type. Further, one of skill in the art would recognize that said fusion polypeptide would not be bound to said Sf9 cells while it is inside said Sf9 cells.

Claim Rejections - 35 USC § 102

Claims 1, 2, 6-8, 10, 11-13, 20-22, 24-27, 34, 35, 37-41, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramshaw et al (US Patent 5866131).

Ramshaw et al teaches a composition comprising the 143B mammalian tumor cell (an antigen bearing target) and further comprising a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence comprising the lectin influenza hemagglutinin (which can bind to any sialic acid – see above) and a second amino acid sequence comprising mouse IL-2 (a ligand for the mouse IL-2 cell surface receptor polypeptides) (see Example 2, in particular). One of skill in the art would describe said fusion polypeptide as "exogenous" to the 143B cells since the construct was recombinantly introduced to said cells (see Example 2, in particular). Further, since said fusion polypeptide is expressed by a polynucleotide construct within said cells, one of skill in the art would describe said fusion polypeptides as "endogenous" to said 143B cells and that it is encoded by a nucleic acid sequence comprised by the cells. Further, Ramshaw et al teaches said fusion polypeptide wherein the first amino acid sequence comprising hemagglutinin is N-terminal to the second amino acid sequence (Figure 6A,

in particular). It is noted that mouse IL-2 would bind mouse IL-2-specific receptor polypeptides on any cell type. Further, one of skill in the art would recognize that said fusion polypeptide would not be bound to said 143B cells while it is produced inside said 143B cells. Further, it is noted that Ramshaw et al teaches methods wherein said virus does not infect humans (Example 2, in particular).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6-8, 10-22, 24-27, 34, 35, 37-41, and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al (International Immunology, 6/01, 13(6):713-721) in view of Air (PNAS, 12/81, 78(12):7639-7643), as evidenced by Raymond et al (Nucleic Acid Research, 10/83, 11(20):7191-7203) and the specification.

Anticipation of claims 1, 2, 6-8, 10-18, 20-22, 24-27, 34, 35, 37-41, and 75-77 by Faulkner et al, as evidenced by the specification and Raymond et al, is described

above. Claim 19 is drawn to the composition of claim 18, wherein said influenza virus is of an H2 or H3 subtype.

Faulkner et al does not specifically teach compositions comprising an antigen bearing target and further comprising a fusion polypeptide said fusion polypeptide comprising a first amino acid sequence comprising at least about 10 contiguous amino acids of hemagglutinin influenza A virus of an H2 or H3 subtype and a second amino acid sequence comprising either mouse interleukin-2 (IL-2) or GM-CSF. However, these deficiencies are made up in the teachings of Air et al.

Air teaches the amino acid sequences hemagglutinin influenza A viruses of an H2 subtype and hemagglutinin influenza A viruses of an H3 subtype (Figure 1, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce a composition comprising an antigen bearing target and further comprising a fusion polypeptide said fusion polypeptide comprising a first amino acid sequence comprising at least about 10 contiguous amino acids of hemagglutinin influenza A virus and a second amino acid sequence comprising either mouse interleukin-2 (IL-2) or GM-CSF, as taught by Faulkner et al, wherein said fusion polypeptide comprising a first amino acid sequence comprising at least about 10 contiguous amino acids of hemagglutinin influenza A virus is of an H2 subtype and compositions wherein said at least about 10 contiguous amino acids of hemagglutinin influenza A virus is of an H3 subtype, as taught by Air, because Faulkner et al teaches the compositions taught by Faulkner et al are to be optimized to produce vaccines with

protective immune responses (left column of page 714, in particular) and Air teaches the polynucleotide sequences of different strains of hemagglutinin, such as H2 and H3 (see Figure 1, in particular), which would require different immune responses. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing compositions comprising an antigen bearing target and further comprising a fusion polypeptide said fusion polypeptide comprising a first amino acid sequence comprising at least about 10 contiguous amino acids of hemagglutinin influenza A virus of an H2 or H3 subtype and a second amino acid sequence comprising either mouse interleukin-2 (IL-2) or GM-CSF because Faulkner et al teaches a method of making compositions comprising an antigen bearing target and further comprising a fusion polypeptide said fusion polypeptide comprising a first amino acid sequence comprising at least about 10 contiguous amino acids of hemagglutinin influenza A virus and a second amino acid sequence comprising either mouse interleukin-2 (IL-2) or GM-CSF (page 714, in particular) and Air teaches the polynucleotide sequences of hemagglutinin influenza A virus of an H2 and H3 subtype. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1-8, 10, 22, 24-33, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ali et al (Cancer Research, 3/15/00, 60:1663-1670) in view of Cantrell et al (PNAS, 9/85, 82:6250-6254).

Anticipation of Claims 1-8, 10, 22, 24-30, 32, and 76 by Ali et al is described above. Claim 31 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide is a ligand for a human GM-CSF receptor. Claim 33 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide comprises human GM-CSF.

Ali et al does not specifically teach a composition comprising an M3 malignant melanoma cell (an antigen bearing target) and further comprising a fusion polypeptide comprising a first N-terminal amino acid sequence comprising genetically inactivated HSV-2 (an amino acid sequence which "can" bind to any sialic acid) and a second amino C-terminal acid sequence comprising human GM-CSF (a ligand for a the human GM-CSF cytokine receptor). However, these deficiencies are made up in the teachings of Cantrell et al.

Cantrell et al teaches the polynucleotide sequence of human GM-CSF (Figure 2, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce a composition comprising an M3 malignant melanoma cell (an antigen bearing target) and further comprising a fusion polypeptide comprising a first N-terminal amino acid sequence comprising genetically inactivated HSV-2 (an amino acid sequence which "can" bind to any sialic acid) and a second amino C-terminal acid sequence comprising GM-CSF, as taught by Ali et al, using the human GM-CSF sequence taught by Cantrell et al because Ali et al teaches that said composition is intended to be developed into a vaccine for clinical use (see last

sentence of abstract of Ali et al, in particular) and one of skill in the art would recognize that human GM-CSF would function better than mouse GM-CSF in the clinic. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a composition comprising an M3 malignant melanoma cell (an antigen bearing target) and further comprising a fusion polypeptide comprising a first N-terminal amino acid sequence comprising genetically inactivated HSV-2 (an amino acid sequence which "can" bind to any sialic acid) and a second amino C-terminal acid sequence comprising human GM-CSF because Ali et al teaches a method of making a composition comprising an M3 malignant melanoma cell (an antigen bearing target) and further comprising a fusion polypeptide comprising a first N-terminal amino acid sequence comprising genetically inactivated HSV-2 (an amino acid sequence which "can" bind to any sialic acid) and a second amino C-terminal acid sequence comprising GM-CSF (page 1665, in particular) and Cantrell et al teaches the polynucleotide sequence of human GM-CSF (Figure 2, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-8, 10-18, 20-22, 24-34, 35, 37-41, and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al (International Immunology, 6/01, 13(6):713-721) in view of Cantrell et al (PNAS, 9/85, 82:6250-6254), as evidenced

by the specification and Raymond et al (Nucleic Acid Research, 10/83, 11(20):7191-7203).

Anticipation of claims 1, 2, 6-8, 10-18, 20-22, 24-27, 34, 35, 37-41, and 75-77 by Faulkner et al, as evidenced by the specification and Raymond et al, is discussed above. Claim 28 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide is a ligand for a mouse GM-CSF receptor. Claim 29 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide comprises at least about five contiguous amino acids of a mouse GM-CSF. Claim 30 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide comprises a mouse GM-CSF. Claim 31 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide is a ligand for a human GM-CSF receptor. Claim 32 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide comprises at least about five contiguous amino acids of a human GM-CSF. Claim 33 is drawn to the composition of claim 1, wherein said ligand for a cell surface polypeptide comprises human GM-CSF.

Faulkner et al does not specifically teach compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising human or mouse GM-CSF. However, these deficiencies are made up in the teachings of Cantrell et al.

Cantrell et al teaches the polynucleotide sequences of human and mouse GM-CSF (Figure 2, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising GM-CSF (page 714 of Faulkner et al, in particular), as taught by Faulkner et al, wherein said GM-CSF is mouse GM-CSF, using a sequence taught by Cantrell et al, because Faulkner et al teaches that the compositions taught by Faulkner et al are to be optimized to produce vaccines with protective immune responses (left column of page 714, in particular) and one of skill in the art would recognize that compositions comprising mouse GM-CSF would function best in the pre-clinical mouse model taught by Faulkner et al (page 714, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising mouse GM-CSF because Faulkner et al teaches a method of producing compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a

fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising GM-CSF (page 714, in particular) and Cantrell et al teaches the mouse GM-CSF sequence (see Figure 2 of Cantrell et al, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Further, one of ordinary skill in the art at the time the invention was made would have been motivated to produce compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising GM-CSF (page 714 of Faulkner et al, in particular), as taught by Faulkner et al, wherein said GM-CSF is human GM-CSF, using a sequence taught by Cantrell et al, because Faulkner et al teaches that the compositions taught by Faulkner et al are to be optimized to produce vaccines with protective immune responses (left column of page 714, in particular) and one of skill in the art would recognize that compositions comprising human GM-CSF would function best in the clinic. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous

amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising human GM-CSF because Faulkner et al teaches a method of producing compositions comprising E coli or immature murine dendritic cells (antigen bearing targets) and a fusion polypeptide comprising a first polypeptide sequence comprising 10 contiguous amino acids of influenza hemagglutinin HA1 domain of strain A/PR/8/34 (a first amino acid sequence which can bind to a sialic acid) and a second polypeptide sequence comprising GM-CSF (page 714, in particular) and Cantrell et al teaches the human GM-CSF sequence (see Figure 2 of Cantrell et al, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1-8, 10, 22, 24-30, 32, 73, 74, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ali et al (Cancer Research, 3/15/00, 60:1663-1670) in view of Natesan (US Patent 6,015,709; 1/18/00), as evidenced by Cantrell et al (PNAS, 9/85, 82:6250-6254).

Anticipation of claims 1-8, 10, 22, 24-30, 32, 73, and 76 by Ali et al, as evidenced by Cantrell et al, is discussed above. Claim 73 is drawn to the composition of claim 1, wherein said fusion polypeptide further comprises a linker interposed between said first and second amino acid sequences. Claim 74 is drawn to the composition of claim 73,

wherein said linker has the formula $(Gly_xSer)_n$, wherein n is an integer between 1 and 15, and x is an integer between 1 and 10.

Ali et al does not specifically teach a linker interposed between said first and second amino acid sequences. However, these deficiencies are made up in the teachings of Natesan.

Natesan teaches linkers, including $(Gly_4Ser)_3$, that would be used to create fusion polypeptides (lines 40-64 of column 28, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to use the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid sequences of the composition taught by Ali et al because said linker would enhance flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of the protein sequences (lines 40-64 of column 28, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a composition using the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid sequences of the composition taught by Ali et al because Natesan teaches methods of adding linkers between polypeptide sequences (lines 40-64 of column 28, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-8, 10-18, 20-22, 24-27, 34, 35, 37-41, and 73-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al (International Immunology, 6/01, 13(6):713-721) in view of Natesan (US Patent 6,015,709; 1/18/00), as evidenced by the specification and Raymond et al (Nucleic Acid Research, 10/83, 11(20):7191-7203).

Anticipation of claims 1, 2, 6-8, 10-18, 20-22, 24-27, 34, 35, 37-41, and 75-77 by Faulkner et al, as evidenced by the specification and Raymond et al, is discussed above.

Faulkner et al does not specifically teach a linker interposed between said first and second amino acid sequences. However, these deficiencies are made up in the teachings of Natesan.

The teachings of Natesan are described above.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid sequences of the composition taught by Faulkner et al because said linker would enhance flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of the protein sequences (lines 40-64 of column 28, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a composition using the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid

sequences of the composition taught by Faulkner et al because Natesan teaches methods of adding linkers between polypeptide sequences (lines 40-64 of column 28, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-8, 10, 11-13, 20-22, 24-27, 34, 35, 37-41, 73, 74, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al (US Patent 5866131) in view of Natesan (US Patent 6,015,709; 1/18/00).

Anticipation of claims 1, 2, 6-8, 10, 11-13, 20-22, 24-27, 34, 35, 37-41, and 76 by Ramshaw is discussed above.

Ramshaw et al does not specifically teach a linker interposed between said first and second amino acid sequences. However, these deficiencies are made up in the teachings of Natesan.

The teachings of Natesan are described above.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid sequences of the composition taught by Ramshaw et al because said linker would enhance flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of the protein sequences (lines 40-64 of column 28). One of

ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing a composition using the $(Gly_4Ser)_3$, linker, as taught by Natesan, interposed between the first and second amino acid sequences of the composition taught by Ramshaw et al because Natesan teaches methods of adding linkers between polypeptide sequences (lines 40-64 of column 28, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-42, and 74-78 of copending Application No. **10/645000**. Although the conflicting claims are not

identical, they are not patentably distinct from each other because, as compared to the instant application, the independent claim of copending application 10/645000 provides a broader limitation for the first amino acid sequence of the fusion polypeptide. Further, "melanoma" tumor cells are not recited as part of the claimed composition of copending Application No. 10/645000; however, these limitations are rendered obvious in the specification of Application No. 10/645000 (see paragraph 438, in particular).

Claims 1-41, and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-29 of copending Application No. **10/224661**. Although the conflicting claims are not identical, they are not patentably distinct from each other because, as compared to the instant application, the independent claim of copending application 10/224661 does not require that the claimed composition comprise something other than a fusion polypeptide. Further, the claims of copending application 10/224661 do not require that said composition comprise an antigen-bearing target, an antigen-bearing target cell, a tumor cell, a melanoma cell, compositions wherein said fusion polypeptide is endogenous or exogenous to said cell, compositions wherein the fusion protein comprises a mouse or human IL-2, fusion proteins that have a linker, fusion proteins that have a linker with the formula $(Gly_xSer)_n$ wherein n is an integer between 1 and 15 and x is an integer between 1 and 10, compositions wherein said fusion protein is or is not bound to a carbohydrate on the antigen-bearing target, or compositions wherein said antigen bearing target is a cell and said composition comprises said fusion polypeptide bound to a carbohydrate on the surface of said cell. However, these deficiencies are rendered

obvious in the specification of 10/224661 (see paragraph 26, 3, 44, 10, 40 of US 20040039156 A1, in particular).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5, 6, and 9-13 of copending Application No. **10/666833**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claim of copending application number 10/666833 is broader than instant independent claim 1. Further, the claims of copending Application No. 10/666833 do not recite that said composition comprises malignant tumor cells, melanoma cells, compositions wherein said fusion polypeptide is exogenous or endogenous to antigen bearing target cells of the composition, compositions wherein the components of the fusion polypeptide in either orientation, compositions wherein the naturally occurring lectin of the fusion polypeptide is hemagglutinin, that said composition comprises at least about 10 contiguous amino acids of an influenza hemagglutinin HA1 domain, compositions wherein said influenza virus is an influenza A virus, compositions wherein said influenza virus is a subtype that does or does not infect humans, compositions wherein said influenza virus is of an H1, H2, or H3 subtype, compositions wherein said influenza virus if from the strain A/PR/8/34, compositions wherein said ligand for a cell surface polypeptide is a ligand for a mammalian cell surface polypeptide, compositions wherein said ligand for a cell surface polypeptide is a ligand for a mouse or human cell surface polypeptide, compositions wherein said ligand is IL-2, fusion proteins that have a linker, fusion proteins that have a linker with the formula $(Gly_xSer)_n$ wherein n is an integer

between 1 and 15 and x is an integer between 1 and 10, compositions wherein said fusion protein is or is not bound to a carbohydrate on the antigen-bearing target, or compositions wherein said antigen bearing target is a cell and said composition comprises said fusion polypeptide bound to a carbohydrate on the surface of said cell. However, these deficiencies are rendered obvious in the specification of 10/666833 (see paragraph 446, 50, 54-64, 11, 42, 20, and 84 of US 20040241137 A1, in particular).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. **10/666871**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the instant claims differ in that they recite the fusion polypeptide taught in claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. 10/666871 in a composition with an antigen bearing target, an antigen bearing target cell, an antigen bearing target tumor cell, and an antigen bearing target melanoma cell, and compositions wherein said fusion protein is endogenous or exogenous to said cell, compositions wherein said fusion polypeptide is bound to a carbohydrate on said antigen bearing target, and compositions wherein at least some of said fusion polypeptide is not bound to said antigen bearing target. However, these deficiencies are rendered obvious in the specification of 10/666871 (see paragraphs 3, 5, 447, 49, 8, and 83 of US 20040122217 A1, in particular).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, and 9-11 of copending Application No. **10/666886**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claim of copending Application No. 10/666886 is broader than the instant claims and does not recite that a component of the fusion polypeptide can bind sialic acid, compositions wherein said antigen bearing cell is a malignant tumor cell, compositions wherein said antigen bearing cell is a melanoma cell, compositions wherein a fusion polypeptide is endogenous or exogenous to the composition's cell, fusion polypeptides created in either orientation, fusion polypeptides comprising a carbohydrate-binding domain of a naturally occurring lectin, fusion polypeptides comprising at least about 10 contiguous amino acids of a hemagglutinin, compositions wherein said hemagglutinin is an influenza virus hemagglutinin, compositions wherein said 10 contiguous amino acids are from the HA1 domain, fusion polypeptides wherein the influenza virus is an influenza A virus, compositions wherein said influenza virus is of a subtype that infects humans, compositions wherein said influenza virus if of a H1, H2, or H3 subtype, compositions wherein the influenza virus is from a strain A/PR/8/34, compositions wehrien said influenza virus is of a subtype that does or does not infect humans, compositions comprising fusion proteins comprising mammalian ligands, compositions comprising fusion proteins comprising mouse or human ligands, compositions comprising fusion proteins comprising IL-2 polypeptides, fusion proteins that have a linker, fusion proteins that have a linker with the formula $(Gly_xSer)_n$ wherein n is an

integer between 1 and 15 and x is an integer between 1 and 10, compositions wherein said fusion protein is or is not bound to a carbohydrate on the antigen-bearing target, or compositions wherein said antigen bearing target is a cell and said composition comprises said fusion polypeptide bound to a carbohydrate on the surface of said cell. However, these deficiencies are rendered obvious in the specification of 10/666886 (see paragraphs 39, 49, 449, 52-63, and 11 of US 20040126357 A1, in particular).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. **10/666898**. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. 10/666898 do not recite an antigen bearing target as part of the composition. Further, claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. 10/666898 do not recite that said antigen bearing target is a cell, a tumor cell, a malignant tumor cell, or a melanoma cell. Further, claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. 10/666898 do not recite that said fusion polypeptide is exogenous or endogenous to said cell or that the fusion polypeptide is bound to a carbohydrate on said antigen bearing target, that at least some of said fusion polypeptide is not bound to said antigen bearing target, or that said antigen bearing target is a cell and said composition comprises said fusion polypeptide bound to a carbohydrate on the surface of the cell. However, these deficiencies are rendered obvious in the specification of 10/666886 (see paragraphs 4, 446, 49, 20, and 83 of US 20040142889 A1, in particular).

Claims 1-41 and 73-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28, 30, 31, 33-41 and 73-77 of copending Application No. **10/666834**. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims -28, 30, 31, 33-41 and 73-77 of copending Application No. 10/666834 are either identical or are species that anticipate the instantly claimed genus.

These are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Summary

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600